K102033

APR - 7 2011

5. 510(k) SUMMARY

SUBMITTER:

B. Braun Melsungen AG Vascular Systems
Sieversufer 8
12359 Berlin
Germany

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DEVICE NAME: Combitrans Monitoring Set

COMMON OR USUAL NAME: Transducer, Blood Pressure, Extravascular

DEVICE CLASSIFICATION: Class II, Product Code DRS 21 CFR 870.2850

PREDICATE DEVICES: Accutrans® Disposable Pressure Monitoring System, Biosensors International, K070710, Class II, DRS, 870.2850

DESCRIPTION: The **Combitrans Monitoring Set** is a pre-calibrated blood pressure transducer designed to transform physiological pressure waveforms into electrical signals using a piezo-resistive sensor. The set is supplied in 6 configurations:

1) **Combitrans Monitoring Set, Venous** (blue striped tubing).
2) **Combitrans Monitoring Set, Arterial** (red striped tubing).
3) **Combitrans Monitoring Set, Pulmonary-Arterial** (yellow striped tubing).
4) **Exadyn Combitrans Monitoring Set** (blue and red striped tubing with additional stopcock for the measurement of venous and arterial blood pressure with one transducer).
5) **Combitrans Add-On Set** (consists only of the transducer, flush device, three-way stopcock and pressure tubing for customized set design and extension.
6) **Combitrans Fixation Tape** (includes a hook and loop band/Velcro fixation tape used to fix the Combitrans transducer to the patient forearm or a stand).

Each set has the same basic intended use and transducer components, but varies according to the features indicated above. With each of the sets, a fluid (saline) filled pressure transmitting catheter can be connected to a venous, arterial or pulmonary-arterial patient catheter that is in indirect contact with the patient's bloodstream.

Each of the six Combitrans Monitoring Sets listed above are composed of the following components: a disposable extra-vascular blood pressure transducer, a sensor that converts hemodynamic pressure waveforms into electrical signals, a transducer cable which is connected to a pressure transmitting catheter system, a flush device and a three-way stopcock. The Combitrans transducer and the sensor function together such that physiologic waveforms are transmitted from a fluid filled cavity inside the transducer housing onto the sensor via a silicone gel cushion.

The Combitrans Monitoring Set finger-activated flush device provides a continuous flush from approximately 3 mL/hr and allows a switch to approximately 300 ml/hr. The Combitrans Monitoring Set interfaces with a standard infusion set and a transducer cable, which transmits electrical signals onto a monitor or into a computer for further processing, graphic presentation or storage. When using the Combitrans device in neonates, infants or small children, the standard gravity infusion set is not used but is exchanged for a syringe pump to control the flow rate, which should not exceed 3 ml/hr.

Combitrans disposable transducers, as well as catheters and infusion systems, are indirectly in contact with the blood stream. They are supplied sterile, individually packaged and for single use only.

Accessories available for use with the Combitrans Monitoring Sets include attachment plates for the attachment of the transducer to an infusion stand. A wide range of interface cables using different plug design and configurations are also available to facilitate storage or visualization of blood pressure measurements on patient monitors.

INTENDED USE:

The B. Braun **Combitrans Monitoring Sets** are intended for the extravascular measurement of venous, arterial, or pulmonary arterial blood pressure by converting hemodynamic waveforms into electrical signals.

The Combitrans flush device provides a continuous flush rate from approximately 3 ml/hr and allows a switch to approximately 300 ml/hr. When using the Combitrans device in neonates, infants or small children. A syringe pump should be used to control the flow rate, which should not exceed 3 ml/hr.

SUBSTANTIAL EQUIVALENCE:

The B. Braun Combitrans Monitoring Sets have the same indications for use, utilize similar technological characteristics and incorporate components similar to the Accutrans Disposable Pressure Monitoring System (K070710). All of the proposed Combitrans Monitoring Sets and the predicate device use an integrated sensor element for the transformation of the physiological waveforms into electrical signals. Both sets utilize non-metallic, biocompatible materials in the housing,. flush device, transmitting components and stopcocks.

Electromagnetic Compatibility

The electromagnetic compatibility of the Combitrans disposable pressure transducer set was evaluated in accordance with the requirements of IEC 60601-2-34 (2000-10) Medical Electrical Equipment Part 2-34: Particular Requirements for the Safety, including Essential performance, of Invasive Blood Pressure Monitoring Equipment."

The Combitrans Monitoring Set fulfills all requirements for electromagnetic compatibility as defined by this standard.

Performance

Performance testing was completed to evaluate the safety and effectiveness of the Combitrans sets, in accordance with the requirements identified in FDA recognized consensus standard ANSI/AAMI BP22-1994/(R)2006: "Blood pressure transducers." Results of performance

testing demonstrate that the Combitrans Monitoring Sets meet all requirements of the standard.

All conical fittings of the Combitrans Monitoring Sets were tested in accordance with the requirements identified in ISO 594-2:1998 "Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings." The Combitrans Monitoring Set fulfilled all requirements for conical luers as defined by this standard.

Biocompatibility

All materials used for the Combitrans disposable pressure transducer sets met requirements for the biological evaluation of medical devices according to the applicable patient contact categories identified in ISO 10993-1:2003.

Conclusions

Test results for electromagnetic compatibility, performance and biocompatibility demonstrate that the Combitrans Monitoring sets are safe and effective for their intended use. Like the Accutrans Disposable Pressure Monitoring System, the Combitrans Monitoring set meets performance requirements of ANSI/AAMI BP22-1994/(R)2006: "Blood pressure transducers" and the biocompatibility requirements identified in ISO 10993-1.

It is concluded that the Combitrans Monitoring Sets are substantially equivalent, and raise no new issues of safety or effectiveness when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

B. Braun Melsungen AG
c/o Ms. Lisa Giaquinto, RAC
Sr. Analyst, Regulatory Affairs
B. Braun Medical, Inc.
901 Marcon Blvd.
Allentown, PA 18109

APR - 7 2011

Re: K102033
Trade/Device Name: Combitrans Monitoring Set with 6 models:
1) Combitrans Monitoring Set, Venous;
2) Combitrans Monitoring Set, Arterial;
3) Combitrans Monitoring Set, Pulmonary-Arterial;
4) Exadyn Combitrans Monitoring Set;
5) Combitrans Add-On Set; and
6) Combitrans Fixation Tape
Regulatory Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II (Two)
Product Code: DRS
Dated: March 17, 2011
Received: March 22, 2011

Dear Ms. Giaquinto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K102033

Device Names: Combitrans Monitoring Sets

Indications For Use:

The B. Braun **Combitrans Monitoring Set** is intended for the extravascular measurement of venous, arterial, or pulmonary arterial blood pressure by converting hemodynamic waveforms into electrical signals.

The Combitrans flush device provides a continuous flush rate from approximately 3 ml/hr and allows a switch to approximately 300 ml/hr. When using the Combitrans device in neonates, infants or small children a syringe pump should be used to control the flow rate, as the flow rate should not exceed 3 ml/hr.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102033